PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
ST. CROIX *et al.*	)	Group Art Unit: 1643
	)	
Serial No. 09/918715	)	
	)	Examiner: C. Yaen
	)	
Filed: August 1, 2001	)	Confirmation No. 2480
	)	
For: **Endothelial Cell Expression Patterns**	)	Docket No. 001107.00134

BRIEF ON APPEAL

U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

A Notice of Appeal was filed on May 29, 2007. Please charge the $ 500 fee for filing this Brief and any other fee which may be due to our Deposit Account No. 19-0733.

REAL PARTY IN INTEREST

The real party in interest in this application is the Johns Hopkins University.

RELATED APPEALS AND INTERFERENCES

A related application is currently on appeal. The related application is S.N. 10/979,159, a continuation of the subject application.

STATUS OF CLAIMS

Claims 1-10 and 18-41 are pending. Claims 1-10 and 18-39 are rejected. Claims 40-41 were not acknowledged by the PTO in the final office action summary. However, they were addressed in the body of the office action as "the new claims" and appear to be similarly rejected. Claims 11-17 are canceled. All pending claims, 1-10 and 18-41, are appealed.

STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment was filed after final rejection. The claims are shown in Appendix 1.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is the sole independent claim. It is directed to an isolated molecule that specifically binds [paragraph 100, page 40, lines 8-9 and 15-19] to an extracellular domain of TEM17 [paragraph 72, page 32, lines 5-12] as shown in SEQ ID NO: 230 [sequence listing at pages 187, line 39 to page 188, line 43]. The molecule is selected from the group consisting of an intact antibody, a single chain variable region (ScFv), a monoclonal antibody, Fab, Fab', and Fab'2 an intact antibody, a single chain variable region (ScFv), a monoclonal antibody, Fab, Fab', and Fab'2 an intact antibody, a single chain variable region (ScFv), a monoclonal antibody, Fab, Fab', and Fab'2 [paragraph 100, lines 11-12].

GROUNDS OF REJECTION TO BE REVIEWED

Whether claims 1-10, and 18-41 are novel under 35 U.S.C. § 102(e) over Drmanac, U.S. 6,667,391.

ARGUMENT

Relevant law

To reject a claim as anticipated, each and every element as set forth in the claim must be either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co., of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987). As discussed below, Drmanac fails to teach each element of the independent claim as well as the dependent claims.

In replying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. App. & Inter. 1990). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Relevant claim recitations

Claim 1, the sole independent claim, requires that the claimed antibody or antibody derivative specifically binds to an extracellular domain of TEM17. The specification defines TEM17 as a protein having the amino acid sequence of SEQ ID NO: 230. The specification defines the extracellular domain as residues 1-426 of SEQ ID NO: 230. See paragraph 100. The specification defines specific binding by comparison of (a) binding of the antibody or antibody derivative to the desired antigen (the extracellular domain of TEM17) to (b) binding of the antibody or antibody derivative to an irrelevant antigen. Paragraph 100, last five lines. Specific binding is defined as at least 2-fold more binding to the appropriate antigen than to the irrelevant antigen.

Claim 38 specifically recites the criterion of at least 2-fold more binding. Claim 39 specifically recites the criterion of at least 5-fold more binding. Claim 40 specifically recites the criterion of at least 7-fold more binding. Claim 41 specifically recites the criterion of at least 10-fold more binding.

Cited prior art

Drmanac teaches a protein sequence (SEQ ID NO: 23) which allegedly shares 42.7 % overall sequence identity with the subject application's SEQ ID NO: 230. See Exhibit 1 of Office Action dated March 13, 2006. Drmanac further teaches an antibody as "specifically recognizing" or "specific for" a polypeptide of its invention. Col. 67, lines 1-23. Drmanac explicitly teaches that its antibodies exclusively bind to SEQ ID NO: 23.

> Another aspect of the invention is an antibody that specifically binds the polypeptide of the invention....The term "specific for" indicates that the variable regions of the antibodies of the invention recognize and bind polypeptides

> of the invention exclusively (i.e., able to distinguish the polypeptide of the invention from other similar polypeptides despite sequence identity, homology, or similarity found in the family of polypeptides), but may also interact with other proteins (for example, S. aureus protein A or other antibodies in ELISA techniques) through interactions with sequences outside the variable region of the antibodies, and in particular, in the constant region of the molecule. Screening assays to determine binding specificity of an antibody of the invention are well known and routinely practiced in the art. For a comprehensive discussion of such assays, see Harlow et al. (Eds), Antibodies A Laboratory Manual; Cold Spring Harbor Laboratory; Cold Spring Harbor, N.Y. (1988), Chapter 6. Col. 66, line 65 to col. 67, line 28, emphasis added.

Drmanac's antibodies which exclusively bind to SEQ ID NO: 23 cannot bind to a protein of SEQ ID NO: 230, *i.e.,* a different protein which shares a mere 43 % homology. If the Drmanac antibodies cannot bind to a protein of SEQ ID NO: 230, then Drmanac cannot anticipate the present claims, each of which recites the element of specifically binding to an extracellular domain of SEQ ID NO: 230. Since anticipation requires that each and every element of a claim must be met (*Verdegaal, supra)*, the failure of Drmanac to fulfill this element prevents Drmanac from anticipating any of the claims.

This explicit teaching of Drmanac's does not require any laboratory experimentation to confirm or demonstrate. Only where a reference does not teach a particular property would an applicant need to experimentally prove that the property is not shared. *In re Best,* 562 F2d 1252, 1255 (C.C.P.A. 1977). This reference however is not silent with respect to the property. This reference states that it does not have the property which is recited in the claim.

The underlying basis of the rejection is that the Drmanac disclosure of SEQ ID NO:23 inherently discloses antibodies which would specifically bind to isolated areas of identity with SEQ ID NO:230, and therefore "specifically bind" to SEQ ID NO:230. For such a rejection to be proper, specific-binding antibodies to SEQ ID NO:230 must necessarily occur upon practice of the Drmanac reference's teaching. *See Ex parte Levy, supra, In re Rijckaert, supra, and In re Robertson, supra.*

Because the areas of identity between SEQ ID NO: 23 and SEQ ID NO: 230 are limited and were not pointed out or taught in the art, antibodies which bind to SEQ ID NO: 230 would not necessarily have resulted from Drmanac's teachings. Thus, the rejection is based only on a theory of probabilities and possibilities of generating antibodies which specifically bind to SEQ ID NO: 230. Such a rejection is clearly improper.

Claims 7, 8, 10, 18, 19, 21, and 26-37

Each of dependent claims 7, 8, 10, 18, 19, 21, and 26-37 contains an additional element which is not taught by Drmanac. These elements are additional reasons that Drmanac does not anticipate these claims.

Claims 7 and 18 each require a cytotoxic moiety bound to the antibody or antibody derivative. Drmanac does not teach such a bound cytotoxic moiety.

Claims 8 and 19 each require a therapeutic moiety bound to the antibody or antibody derivative. Drmanac does not teach such a bound therapeutic moiety.

Claims 10 and 21 each require an anti-tumor agent bound to the antibody or antibody derivative. Drmanac does not teach such a bound anti-tumor agent.

Claims 26-37 each teach that the antibody or antibody derivative specifically binds to particular residues of TEM17. Drmanac does not teach binding to any such particular residues.

CONCLUSION

Drmanac does not teach the claimed subject matter. Drmanac explicitly and particularly teaches that its antibody and antibody derivatives exclusively bind to a different protein than TEM17. That different protein shares only 43 % of its amino acid residues with the recited TEM17. Thus even if Drmanac's different protein might permit one of skill in the art to accidentally create an antibody or antibody derivative that cross-reacted with TEM17, Drmanac's explicit teachings exclude such an antibody. The rejection is based on nothing more than possibilities and probabilities. These are insufficient bases for an anticipation rejection.

Respectfully submitted,
BANNER & WITCOFF, LTD.

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By: /Sarah A. Kagan/
Sarah A. Kagan
Registration No. 32,141

APPENDIX 1. APPEALED CLAIMS

1. An isolated molecule selected from the group consisting of: an intact antibody, a single chain variable region (ScFv), a monoclonal antibody, Fab, Fab', and Fab'2, wherein said molecule specifically binds to an extracellular domain of TEM 17 as shown in SEQ ID NO: 230.

2. The isolated molecule of claim 1 which is an intact antibody molecule.

3. The isolated molecule of claim 1 which is a single chain variable region (ScFv).

4. The isolated molecule of claim 1 which is a monoclonal antibody.

5. The isolated molecule of claim 1 which is a humanized antibody.

6. The isolated molecule of claim 1 which is a human antibody.

7. The isolated molecule of claim 1 which is bound to a cytotoxic moiety.

8. The isolated molecule of claim 1 which is bound to a therapeutic moiety.

9. The isolated molecule of claim 1 which is bound to a detectable moiety.

10. The isolated molecule of claim 1 which is bound to an anti-tumor agent.

11-17. (Cancelled)

18. The isolated molecule of claim 4 which is bound to a cytotoxic moiety.

19. The isolated molecule of claim 4 which is bound to a therapeutic moiety.

20. The isolated molecule of claim 4 which is bound to a detectable moiety.

21. The isolated molecule of claim 4 which is bound to an anti-tumor agent.

22. The isolated molecule of claim 6 which is bound to a cytotoxic moiety.

23. The isolated molecule of claim 6 which is bound to a therapeutic moiety.

24. The isolated molecule of claim 6 which is bound to a detectable moiety.

25. The isolated molecule of claim 6 which is bound to an anti-tumor agent.

26. The isolated molecule of claim 1 which specifically binds to residues 137-244 or 280-344 of TEM17.

27. The isolated molecule of claim 2 which specifically binds to residues 137-244 or 280-344 of TEM17.

28. The isolated molecule of claim 3 which specifically binds to residues 137-244 or 280-344 of TEM17.

29. The isolated molecule of claim 4 which specifically binds to residues 137-244 or 280-344 of TEM17.

30. The isolated molecule of claim 5 which specifically binds to residues 137-244 or 280-344 of TEM17.

31. The isolated molecule of claim 6 which specifically binds to residues 137-244 or 280-344 of TEM17.

32. The isolated molecule of claim 1 which specifically binds to residues 19-426 of TEM17.

33. The isolated molecule of claim 2 which specifically binds to residues 19-426 of TEM17.

34. The isolated molecule of claim 3 which specifically binds to residues 19-426 of TEM17.

35. The isolated molecule of claim 4 which specifically binds to residues 19-426 of TEM17.

36. The isolated molecule of claim 5 which specifically binds to residues 19-426 of TEM17.

37. The isolated molecule of claim 6 which specifically binds to residues 19-426 of

TEM17.

38. The isolated molecule of claim 1 wherein said molecule binds to TEM17 at least 2 times more than to irrelevant antigen or antigen mixture.

39. The isolated molecule of claim 1 wherein said molecule binds to TEM17 at least 5 times more than to irrelevant antigen or antigen mixture.

40. The isolated molecule of claim 1 wherein said molecule binds to TEM17 at least 7 times more than to irrelevant antigen or antigen mixture.

41. The isolated molecule of claim 1 wherein said molecule binds to TEM17 at least 10 times more than to irrelevant antigen or antigen mixture.

APPENDIX 2. EVIDENCE RELIED UPON

none

APPENDIX 3. RELATED PROCEEDINGS

Appeal of S.N. 10/979,159 to the Board of Patent Appeals and Interferences is pending.